

### REMARKS

Applicant respectfully requests reconsideration. Claims 1-101 and 169-193 were previously pending in this application. By this amendment, Applicant is canceling claims 1-47, 49, 50, 54, 57, 58, 62, 91-101 and 169-186 without prejudice or disclaimer. Claims 48, 51-53, 55, 59-61, 63, 64, 71, 73, 76, 78, 79, 187, 188 and 190-193 have been amended. New claims 194-265 have been added. Support for the claim amendments and newly added claims can be found throughout the specification (See, e.g., page 8, lines 10 and 11; page 35, lines 12-19; page 36, lines 1-3 and lines 23-28; page 75, lines 20-26) and in the claims as originally filed. As a result, claims 48, 51-53, 55, 56, 59-61, 63-90 and 187-265 are pending for examination with claims 48, 187, 188, 208, 244, 245, 250, 261 and 262 being independent claims.

Applicant reserves the right to pursue any subject matter canceled herein in this or one or more continuing applications. No new matter has been added.

### Priority

The Examiner has stated that claims 1-101 and 187-193 do not properly benefit under §§ 119 and/or 120 by the earlier filing dates of the priority documents claimed, since these claims, according to the Examiner, lack adequate written description and a sufficiently enabling disclosure. The Examiner has concluded that the effective filing date of the claims is October 27, 2003.

Applicant notes for the record, that although the claims have been canceled or amended as described herein, Applicant does not concede the correctness of the Examiner's conclusion in regard to the adequacy of the disclosure of the priority documents. Applicant further does not concede that the Examiner is correct in the determination of the effective filing date of the rejected claims.

### Objections to the Drawings

The Examiner objected to the drawing set forth as Figure 13, as according to the Examiner, the figure depicts nucleic acid and amino acid sequences, which are not identified by sequence identification numbers.

Applicant respectfully thanks the Examiner for bringing this to Applicant's attention. The description of Figure 13 in the **Brief Description of the Drawings** section of the specification has been amended to provide sequence identifying numbers for the sequences represented. In addition, a corrected sequence listing is provided herewith to include the sequences of Figure 13.

Reconsideration and withdrawal of this objection is respectfully requested.

#### Objections to the Specification

The Examiner objected to the specification, as according to the Examiner, the sequences in Figure 13 are not identified by sequence identification numbers, either in the figure or in the brief description of the figure.

Again, as stated above, Applicant respectfully thanks the Examiner for bringing this to Applicant's attention. Also, as described above, the description of Figure 13 in the **Brief Description of the Drawings** section of the specification has been amended, and a corrected sequence listing is provided herewith.

Reconsideration and withdrawal of this objection is respectfully requested.

The Examiner also objected to the specification because of the alleged use of improperly demarcated trademarks.

Applicant respectfully thanks the Examiner for bringing this to Applicant's attention. Accordingly, the specification has been amended so that the trademarks have been properly demarcated by capitalization. Applicant notes that the Examiner has indicated that trademarks may be demarcated by capitalization. Accordingly, Applicant believes that with the demarcation of the trademarks, the requirement according to MPEP 608.01(v) is satisfied. The use of the trademarks in the instant specification is such that the identity of the products/services referred to by the trademarks is clear.

Reconsideration and withdrawal of this objection is respectfully requested.

The Examiner has also been objected to hyperlink(s) embedded in the specification.

Again, Applicant respectfully thanks the Examiner for bringing this to Applicant's attention. The specification has been amended to remove the hyperlink(s) in compliance with the requirements of MPEP 608.01(p), paragraph 1.

Reconsideration and withdrawal of this objection is respectfully requested.

#### Claims Objections

The Examiner has objected to claims 20, 64 and 68 as allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant respectfully disagrees. According to CFR 1.75(c), a dependent claim must further limit the claim or claims from which it depends and shall be construed to include all the limitations of the claim incorporated by reference. The claims objected to by the Examiner satisfy these requirements, as each of claims 20, 64, and 68 do indeed further limit the scope of and include all of the limitations of the claims from which they depend, respectively. For example, claim 19 is directed to at least one of a defined group of adjuvants, which includes alum. Claim 20 recites that the adjuvant is alum. Therefore, claim 20 further limits claim 19 in that instead of the adjuvant being at least one of a group, it is a specific member of the recited group. The situation of claims 64 and 68, as pending prior to this amendment, is analogous to that of claim 20.

Accordingly, withdrawal of this objection is respectfully requested.

#### Rejection under 35 U.S.C. §101

The Examiner has rejected claim 193 under 35 U.S.C. §101 because the claimed invention allegedly is not supported by a specific and substantial asserted utility, a credible asserted utility, or a well-established utility.

Applicant respectfully traverses. However, in the interest of expediting prosecution and without conceding the correctness of the Examiner's rejection, Applicant has amended the rejected claim such that "pharmaceutical" is no longer recited in the preamble. Accordingly, it is believed that this rejection is now moot. Applicant maintains that the compositions to which the claims as amended are directed include, but are not limited to, those that are for a pharmaceutical purpose.

While Applicant has amended the claims, and believes that this rejection is now moot, Applicant states the following for the record. In order to satisfy the utility requirement, only one assertion of utility for the claimed invention is required. *Brooktree Corp v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 USPQ2d 1401, 1412 (Fed. Cir. 1992.) Applicant has, in fact, provided a number of substantial and specific uses for the claimed invention. For example, on page 42, lines 8-15, it is provided that the PSMA compositions can be used to elicit or enhance an immune response, to treat a subject suffering from cancer, or to immunize an animal to raise antibodies to dimeric PSMA. Such assertions are sufficient to satisfy the utility requirement.

Further, in order to violate the utility requirement, the claimed invention must be shown to be “totally incapable of achieving a useful result.” *Brooktree Corp v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 USPQ2d 1401, 1412 (Fed. Cir. 1992.) Applicant maintains that this has not been demonstrated.

Reconsideration and withdrawal of this rejection is respectfully requested.

#### Rejections under 35 U.S.C. §112

Claim 193 has also been rejected under 35 U.S.C. §112, first paragraph, as allegedly one skilled in the art would not know how to use the claimed invention, since it is allegedly not supported by a specific and substantial asserted utility, a credible asserted utility, or a well-established utility.

Applicant respectfully traverses for the reasons provided above. Based on at least the teachings provided in the instant application, one of ordinary skill in the art would know that the claimed compositions can be used at least for the uses as provided immediately above. Nevertheless, as the claim has been amended to remove the recitation of “pharmaceutical” from the preamble, this rejection is believed to be moot.

Reconsideration and withdrawal of this rejection is respectfully requested.

Claims 1-101 and 187-193 have been rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

(a) The Examiner has argued that claims 1-101 and 187-193 are indefinite for using the term “PSMA” as the sole means of identifying the polypeptide to which the claims refer. Without conceding the correctness of this rejection and solely in the interest of expediting prosecution of the instant application, Applicant has either canceled the rejected claims or amended them such that PSMA protein is defined by reference to SEQ ID NO: 1. Further, the newly added claims also define PSMA protein by reference to SEQ ID NO: 1. Therefore, the rejection of the claims on this basis is believed to be moot.

(b) and (c) The Examiner has argued that claims 3 and 4 are indefinite for the parenthetical recitation of certain sequences. Without conceding the correctness of this rejection and solely in the interest of expediting prosecution of the instant application, Applicant has canceled claims 3 and 4. Further, the newly added claims refer to specific sequences without the use of parenthetical recitations. Therefore, the rejection of the claims on this basis is believed to be moot.

(d) and (h) The Examiner has argued that claims 19, 30 and 78 are indefinite for containing trademark/trade names. Without conceding the correctness of this rejection and solely in the interest of expediting prosecution of the instant application, Applicant has canceled claims 19 and 30 and amended claim 78. Claim 78 has been amended such that “polysorbate 20” is recited instead of “Tween20” and “polysorbate 80” is recited instead of “Tween80”. Further, in new claims 204, 231 and 258, instead of “Enhanzyn”, “Detox-B” is recited, and instead of “montanide”, “manide-oleate adjuvant” is recited. Accordingly, it is believed that the rejection of the claims on this basis is now moot.

(e), (f), (g), (i), (m), (q), (r), (s) and (t) The Examiner has rejected claims 19, 25, 28, 30, 55-61, 73, 76, 78 and 101 as allegedly being indefinite for the recitation of “a combination thereof”. Without conceding the correctness of this rejection and in the interest of expediting prosecution, Applicant has either canceled or amended the rejected claims to remove the recitation of “a combination thereof”. Further, none of the newly added claims recite “a combination thereof”. Accordingly, it is believed that the rejection of claims on this basis is now moot.

(j) The Examiner has argued that claims 43-47 are indefinite for reciting that the composition comprises less than 35% of a monomeric PSMA protein without indicating how the

percentage is calculated. Without conceding the correctness of this rejection and in the interest of expediting prosecution, Applicant has canceled the rejected claims. Accordingly, it is believed that the rejection of the claims on this basis is now moot. Applicant notes for the record, however, that it would be apparent to one of ordinary skill in the art that the percentage of monomeric PSMA protein can be determined on a weight per weight basis, such as with the use of BN-PAGE as described in the instant specification.

(k), (l), (o) and (p) The Examiner has argued that claim 50-71 are indefinite because the phrase “the solution that promotes or preserves dimeric association of PSMA protein” does not have antecedent basis from the reference to multimeric association. According to the Examiner, multimeric association is not necessarily dimeric association. Applicant respectfully disagrees with this rejection, as dimeric is a specific form of multimeric association. However, without conceding the correctness of the Examiner’s rejection and in the interest of expediting prosecution, Applicant has amended the claims such that this phrase is no longer recited. Further, none of the newly added claims recite this phrase. Accordingly, it is believed that the rejection of the claims on this basis is now moot. Applicant notes for the record, however, that the solutions as described in the amended claims include those that promote or preserve the multimeric (e.g., dimeric) association of PSMA protein.

(n) The Examiner has argued that claims 55-61 are indefinite because of the recitation of “cationic component” and “anionic component”, for which there is allegedly insufficient antecedent basis in the preceding claims. The Examiner makes this conclusion because the “solution”, according to the Examiner, is not necessarily an aqueous one in which the salt is soluble. Applicant respectfully disagrees. Applicant notes that as the term “solution” can be an aqueous one in which the salt is soluble, the terms are sufficiently definite. Nevertheless, without conceding the correctness of this rejection and in the interest of expediting prosecution, Applicant has amended the rejected claims such that “cationic component” and “anionic component” are no longer recited. Further, the newly added claims likewise do not recite “cationic component” or “anionic component”. Accordingly, it is believed that the rejection of the claims on this basis is now moot.

Reconsideration and withdrawal of this rejection is respectfully requested.

The Examiner has rejected claims 1-101 and 187-193 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. According to the Examiner, the rejected claims contain subject matter which was not described in the specification in such a way as to reasonable convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner has argued that sufficient identifying characteristics of “PSMA protein” have not been provided to demonstrate possession of the claimed genus. The Examiner has also argued that an adequate written description of the genus of solutions that preserve or promote the multimeric association of PSMA is not provided. Finally, the Examiner has argued that the specification does not provide an adequate written description for the “stable” compositions of rejected claims 91-94.

Applicant respectfully traverses. However in the interest of expediting prosecution, and without conceding the correctness of this rejection, Applicant has either canceled or amended the rejected claims.

In regard to “PSMA protein”, Applicant has amended claims 48, 187 and 188 such that the claims recite that the sequence of the PSMA protein comprises the sequence as set forth as SEQ ID NO: 1, or a portion thereof. Applicant maintains that with this reference to a specific sequence, a skilled artisan would be able to envision, recognize and distinguish the PSMA proteins of the amended claims from others, as the members of the genus do share a particular identifying structural feature.

In regard to the genus of solutions that preserve or promote the multimeric association of PSMA, Applicant has amended the claims such that specific components and features of a solution are recited. It is noted, that such a solution can still be a solution that serves the function of preserving or promoting multimeric (e.g., dimeric) association of PSMA. It is believed that one of ordinary skill in the art would recognize that the inventor(s) at the time the application was filed had possession of compositions that include such solutions.

Finally, in regard to “stable”, Applicant has canceled claims 91-94.

Applicant believes that this rejection is now moot and respectfully requests its reconsideration and withdrawal.

The Examiner has also rejected claims 1-101 and 187-192 under 35 U.S.C. §112, first paragraph, because, according to the Examiner, the specification does not reasonably provide enablement for making and using the claimed subject matter. The Examiner bases this rejection on the use of the term “PSMA protein”, which the Examiner argues includes functionally equivalent proteins. The Examiner has also argued that the disclosure does not reasonably enable the skilled artisan to make and use the widely varying solutions that promote or preserve multimeric association of PSMA. Finally, the Examiner has argued that the specification does not provide sufficient teachings as to how the compositions and properties of the solutions can be “tweaked” to arrest the system to make compositions with specific percentages of PSMA in dimer and monomer form.

Applicant respectfully traverses. However, without conceding the correctness of the rejection and in the interest of expediting prosecution, Applicant has canceled or amended the rejected claims. It is noted that the pending claims are now directed to compositions comprising PSMA protein defined by reference to a particular sequence (SEQ ID NO: 1). Further, instead of generally referring to solutions that preserve or promote multimeric association of PSMA, specific components and features of a solution are recited. Finally, claims that referred to specific percentages of dimeric and monomeric PSMA have been canceled. Applicant notes for the record, however, that the solutions of the amended claims include those that can promote or preserve multimeric (e.g., dimeric) association of PSMA, and the compositions of the amended claims include those with specific percentages of PSMA in dimeric and monomeric form.

As the Examiner has indicated that compositions comprising the polypeptide of SEQ ID NO: 1 or a fragment thereof and a kit comprising such a composition are enabled, Applicant believes that the compositions of the amended claims are likewise enabled, as the claims refer to specific PSMA polypeptides and recite specific components and features of the compositions.

Accordingly, Applicant believes that this rejection is now moot, and respectfully requests reconsideration and withdrawal of this rejection.

#### Rejections Under 35 U.S.C. §102

Claims 1-12, 17, 23, 24, 26, 29-50, 54, 61-63, 71, 72, 74, 77-90 and 193 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Carter et al. (*Proc. Natl. Acad. Sci.*



USA. 1996 Jan; 93: 749-753) as evidenced by Slusher et al. (*J. Biol. Chem.* 1990 Dec 5; 265(34): 21297-21301), Robinson et al. (*J. Biol. Chem.* 1987 Oct 25; 262(30): 14498-14506) and Schulke et al. (*Proc. Natl. Acad. Sci. USA.* 2003 Oct 28; 100(22): 12590-12595).

Applicant respectfully traverses. However, without conceding the correctness of this rejection and in the interest of expediting prosecution of the instant application, the rejected claims have been canceled or amended such that they are directed to compositions comprising a dimer of PSMA protein in a solution that has a pH in the range of 6 to 7.5, wherein the composition further comprises at least one type of metal ions, and at least one salt, wherein the salt is present at a concentration in the range of 100mM to 300mM, and wherein the sequence of each PSMA protein comprises the sequence set forth as SEQ ID NO: 1, or a portion thereof. Applicant notes that Carter et al. do not provide or make obvious such compositions.

Reconsideration and withdrawal of this rejection is respectfully requested.

#### Double Patenting

The Examiner has provisionally rejected claims 1-12, 17, 18, 21, 43-47 and 193 as allegedly being unpatentable over claims of copending application no. 10/395894 on the ground of nonstatutory obviousness-type double patenting. The Examiner has also provisionally rejected claims 1-13, 17-26, 29, 31-52, 54-58, 60-66, 68, 69, 71-74, 77, 79-90, 95-97, 99-101 and 187-193 as allegedly being unpatentable over claims of copending application no. 10/976352 on the ground of nonstatutory obviousness-type double patenting.

These *provisional* double patenting rejections are based on the aforementioned co-pending unallowed applications. In view of the unallowed state of the co-pending applications, Applicant proposes that these rejections be deferred and maintains the right to subsequently address these rejections (See, MPEP §804), if necessary.

Further, in regard to application no. 10/976352 and the alleged requirement to demonstrate common ownership, without conceding the correctness of the Examiner's arguments, it is noted that Applicant is in the process of correcting the inventorship for the instant application. Once the inventorship is corrected, the inventors of the claimed invention of the instant application and the claimed invention of application no. 10/976352 will be the same.

Accordingly, the requirement to demonstrate common ownership under 35 U.S.C. §103(c) and 37 CFR 1.78(c) will not apply.

Accordingly, Applicant respectfully requests that this issue be deferred until the inventorship of the instant application is corrected.

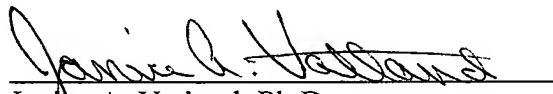
Finally, in regard to the Examiner's statement(s) pertaining to art made of record and not relied upon, Applicant, for the record, does not concede the correctness of the Examiner's characterization of any of the listed references.

### **CONCLUSION**

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,



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